

#8/008
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re application of:

MOSE LARSEN *et al.*

Appl. No. 09/297,040

§ 371 Date: July 21, 1999

For: **Diabetes-Mediating Proteins and
Therapeutic Uses Thereof**

Art Unit: 1633

Examiner: Kaushal, S.

Atty. Docket: 2012.0390004/JAG/TJS
(formerly 0785.0390004/JAG/TJS)

Reply To Restriction Requirement

Commissioner for Patents
Washington, D.C. 20231

Sir:

In reply to the Office Action dated October 4, 2000, requesting an election of one invention to prosecute in the above-referenced patent application, the period for reply having been extended five (5) months by petition and payment of the appropriate fee, Applicants hereby provisionally elect to prosecute the invention of Group II, represented by claims 7-11. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made with traverse.

Applicants point out that claims 12-13 are not assigned to any of the restriction groups. Accordingly, Applicants request at a minimum that the present Restriction Requirement be withdrawn and the restriction reformulated so as to address all of the claims. Applicants will nevertheless address the merits of the present Restriction Requirement.

The above-captioned application is a national stage of a PCT application; therefore, PCT unity of invention rules apply. As acknowledged by the Examiner, an

international or national stage application containing claims to different categories of invention has unity of invention if, as stated in MPEP 37 C.F.R. § 1.475(b), the claims are drawn only to one of the following combinations of categories: 1) a product and a process specially adapted for the manufacture of said product; 2) a product and a process for use of said product; 3) a product, a process specially adapted for the manufacture of said product, and a use of said product; 4) a process and an apparatus or means specifically designed for carrying out said process; or 5) a product, a process adapted for the manufacture of said product, and an apparatus or means specifically adapted for carrying out said process.

The diabetes-mediating proteins of Group II (claims 7-11) are characterized as exhibiting an altered expression during the development of diabetes, relative to expression of the same protein in the absence of diabetes. As will be understood from the application document as a whole, the presence of these proteins indicate diabetes in a mammal. One characteristic feature is thus their ability to serve as indicator- or marker proteins for diabetes.

Claims 12-13 (omitted from any Group) are drawn to the use of said proteins for their characteristic properties in a comparative analysis. Claims 12-13 are thus drawn to a process for the use of the proteins. Thus, claims 7-11 and claims 12-13 fall within the combination of category (2) described above.

Moreover, claims 22-23 relate to the use of the diabetes-mediating proteins to treat or prevent diabetes or a diabetes-related disorder, comprising administering said protein. Claims 22-23 also fall within the combination of category (2) above along with claims 7-11 and 12-13.

Claim 20 relates to the use of an antibody to the proteins in a method of treating diabetes. The antibody and the protein have a complementary relationship analogous to a plug and socket in PCT Administrative Instructions, Annex B, part 2, Example 8, or between transmitter and receiver in Example 9 thereof.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the Restriction Requirement, and a reformulation of the restriction groups.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such

extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

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